NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

WYETH, CARDINAL HEALTH, INC., CARDINAL PTS, LLC, CARDINAL HEALTH 409, INC., f/k/a R.P. SCHERER CORP., and R.P. SCHERER TECHNOLOGIES, INC.	
Plaintiffs/Counterdefendants,	**MEMORANDUM OPINION**
v.	
RANBAXY LABORATORIES LIMITED, RANBAXY, INC., and RANBAXY PHARMACEUTICALS INC.,	Civ. No. 05-2252 (GEB)
Defendant/Counterclaimants.	

BROWN, Chief Judge

This matter comes before the Court upon Defendants Ranbaxy Laboratories Limited, Ranbaxy, Inc. and Ranbaxy Pharmaceuticals Inc.'s (collectively referred to as "Ranbaxy") Motion for Judgment on the Pleadings with Respect to Plaintiff's Allegation of Willful Infringement. The Court decided the motion based on the parties' written submissions and without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons discussed herein, the Court grants-in-part and denies-in-part Ranbaxy's motion.

I. BACKGROUND

This is a patent infringement action arising under the Hatch-Waxman Act. Plaintiffs Wyeth and Cardinal Health, Inc., Cardinal Health PTS, LLC, and Cardinal Health 409, Inc. f/k/a R.P.

Scherer Technologies, Inc. (collectively "Wyeth") engage in the business of developing, marketing and selling pharmaceutical products. Ranbaxy produces and markets generic versions of pharmaceutical drugs. Plaintiff R.P. Scherer Technologies, Inc., a subsidiary of Cardinal Health, Inc., is the assignee of two patents, namely U.S. Patent No. 5,071,643 (the "'643 Patent") and U.S. Patent No. 5,360,615 (the "'615 Patent"). Wyeth licenses both patents and has listed the patents in the Electronic Orange Book ("the Orange Book").[1] The Orange Book indicates that the patents expire on December 10, 2008 and pediatric exclusivity expires on June 10, 2009. (Compl. ¶ 9).

On December 23, 2004, Ranbaxy filed Abbreviated New Drug Application ("ANDA") No. 77-484 pursuant to § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.§ 355(j). Ranbaxy seeks approval from the FDA to manufacture, use and sell Ibuprofen and Pseudoephedrine Hydrochloride Capsules (200mg/30mg). Ranbaxy asserted in its ANDA that these capsules are bioequivalent to Wyeth's ADVIL® COLD and SINUS LIQUI-GELS. Ranbaxy notified Wyeth of its ANDA filing by letter dated March 9, 2005. In its notice letter, Ranbaxy indicated that the ANDA contained a Paragraph IV Certification which certifies Ranbaxy's belief that the commercial manufacture, use or sale of its Ibuprofen and Pseudoephedrine Hydrochloride Capsules would not infringe the '643 and '615 Patents.[2]

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[1] The Orange Book refers to a book entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" in which the Food and Drug Administration ("FDA") lists patents claiming drugs that relate to New Drug Applications ("NDA"). *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1325-26 (Fed. Cir. 2003).

[2] Pursuant to the Hatch-Waxman Act, an ANDA shall contain a certification with respect to each patent which claims the listed drug that is the subject of the ANDA. The certification shall certify:

(I) that such patent information has not been filed,
(II) that such patent has expired,

On April 22, 2005, Wyeth filed suit in this Court against Ranbaxy alleging that the submission of its ANDA constitutes infringement of one or more claims of the '643 and '615 Patents pursuant to 35 U.S.C. § 271(e)(2). (Compl. ¶ 13). Ranbaxy answered on June 30, 2005 and asserted counterclaims, seeking declaratory judgment that the patents are not infringed and are invalid. Wyeth filed its Answer to the counterclaims on July 20, 2005. On May 10, 2006, Ranbaxy filed the instant motion. Ranbaxy asserts that Wyeth's allegation of willful infringement fails as a matter of law, and must therefore be dismissed.

II. DISCUSSION

A. Standard for Motion for Judgment on the Pleadings Pursuant to Rule 12(c).

A defendant may move to dismiss a complaint or parts of a complaint before or after filing an answer. *See* FED. R. CIV. P. 12(b)(6) and (c). A motion made before an answer is filed is a motion to dismiss pursuant to Federal Rule Civil Procedure 12(b)(6). A motion made after an answer is filed is a motion for judgment on the pleadings pursuant to Rule 12(c).[3] "A defense of

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> (III) of the date on which such patent will expire, or
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .

21 U.S.C. § 355 (j)(2)(A)(vii); *see Allergan*, 324 F.3d at 1326.

[3] Rule 12(c) provides:

> Motion for Judgment on the Pleadings. After the pleadings are closed but within such time as not to delay the trial, any party may move for judgment on the pleadings. If, on a motion for judgment on the pleadings, matters outside the pleadings are presented to and not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56, and all

failure to state a claim upon which relief can be granted . . . may be made in . . . [a] motion for judgment on the pleadings." *See* FED. R. CIV. P. 12(h)(2). Here, Ranbaxy's motion was filed after it filed its answer.

The standard under which the Court must analyze the plaintiff's complaint and the defendants' arguments in a Rule 12(c) motion for judgment on the pleadings is the same as the standard in a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). *See* FED. R. CIV. P. 12(h)(2); *see also Turbe v. Gov't of the Virgin Is.*, 938 F.2d 427, 428 (3d Cir. 1991); *Inst. for Scientific Info., Inc. v. Gordon & Breach, Sci. Publishers, Inc.*, 931 F.2d 1002, 1006 (3d Cir. 1991), *cert. denied*, 502 U.S. 909 (1991). Like Rule 12(b)(6), Rule 12(c) requires the Court to "accept the allegations in the complaint as true, and draw all reasonable factual inferences in favor of the plaintiff." *Turbe*, 938 F.2d at 428 (citing *Unger v. Nat'l Residents Matching Program*, 928 F.2d 1392, 1394-95 (3d Cir. 1991)). A complaint may be dismissed for failure to state a claim where it appears beyond any doubt that no relief could be granted under any set of facts which could be proved consistent with the allegations. *See Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984).

Legal conclusions made in the guise of factual allegations, however, are given no presumption of truthfulness. *See Papasan v. Allain*, 478 U.S. 265, 286 (1986); *see also Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) ("[A] court need not credit a complaint's 'bald assertions' or 'legal conclusions' when deciding a motion to dismiss").

> parties shall be given reasonable opportunity to present all materials made pertinent to such a motion by Rule 56.

FED. R. CIV. P. 12(c).

B. Willful Infringement in the Context of ANDA Litigation

Ranbaxy argues that under the Patent Act and Federal Circuit precedent, a claim for willful infringement is not actionable in ANDA cases. Citing *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004), Ranbaxy asserts that "the mere filing of an ANDA cannot constitute grounds for a willful infringement determination." *Id.* at 1349. Ranbaxy argues that the Federal Circuit characterized the filing of an ANDA as "jurisdiction-conferring," and thus infringement based solely on the filing of the ANDA is artificial. Ranbaxy further asserts that it cannot be liable for willful infringement because the generic pharmaceutical products for which they seek FDA approval have not yet entered the market, and thus no damages exist at this time. Lastly, Ranbaxy maintains that Wyeth has not made allegations that would render the case exceptional under 35 U.S.C. § 285 – another means by which Wyeth could argue that willful infringement allegations are proper.

In response, Wyeth argues that Ranbaxy misconstrues the *Glaxo* holding as a pronouncement by the Federal Circuit that an ANDA filer can never be liable for willful infringement. Wyeth contends that this position is incorrect. According to Wyeth, *Glaxo* permits a finding of willful infringement based on "the act of filing an ANDA taken in combination with any of a number of other circumstances such as copying the patented invention . . . ." (Pl.'s Opp'n at 2). Wyeth contends that this is the basis upon which it intends to prove its willfulness claim against Ranbaxy. In particular, Wyeth asserts that Ranbaxy already produced certain documents which indicate that "Ranbaxy actually copied the method in the '643 and'615 [P]atents in making its generic product." (*Id.* at 3). Wyeth argues that deliberate copying of a patented invention is a factor that should be considered in determining whether enhanced damages are warranted. Thus, Wyeth maintains that it should be entitled to further develop this evidence to prove its willfulness claim.

The Federal Circuit has addressed the issue of willful infringement in the context of ANDA litigation in two cases – *Glaxo* and *Yamanouchi*, 231 F.3d 1339 (Fed. Cir. 2000). In both cases, the Federal Circuit examined two key provisions of the Patent Act. First, the court discussed 35 U.S.C. § 271(e)(2) which provides that:

> It shall be an act of infringement to submit . . . an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271 (e)(2). *In Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990), the Supreme Court noted that the purpose of this provision is to create an "artificial[] act of infringement for a very limited and technical purpose that relates only to certain drug applications." *Id.* at 676. In light of this characterization, the Federal Circuit subsequently characterized 35 U.S.C. § 271(e)(2) as a "jurisdiction-conferring" statute which allows district courts to exercise jurisdiction pursuant to 28 U.S.C. § 1338(a) in cases where an ANDA has been filed. *See Glaxo*, 376 F.3d at 1351; *see also Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003).

The Federal Circuit also referenced § 271(e)(4) which defines a limited number of remedies that are available to an innovator company who asserts infringement under § 271(e)(2). Specifically, § 271(e)(4) provides:

> For an act of infringement described in paragraph (2)--
>
> (A) the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . . , and
>
> (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . . .

35 U.S.C. § 271(e)(4). Notably, in addition to these remedies, the Act also provides that "a court *may award attorney fees under section 285*."[4] *Id.* (emphasis added).

In *Glaxo*, the Federal Circuit reversed the district court's award of attorney fees which was based on a finding of willful infringement under § 271(e)(2). The Federal Circuit determined that the district court committed clear legal error by concluding that "the mere filing of an ANDA could form the basis of a willful infringement finding." *Glaxo*, 376 F.3d at 1351. The court noted that there was no finding that the ANDA filer engaged in litigation misconduct or filed a baseless Paragraph IV certification, which was the case in *Yamanouchi* as discussed below. Rather, the award of attorneys fees was based solely on an improper finding of willful infringement. This constituted legal error.

In contrast, the Federal Circuit upheld an award of attorneys fees in *Yamanouchi*. The district court in *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc.*, 21 F. Supp. 2d 366 (S.D.N.Y. 1998), determined that Danbury's conduct, the ANDA filer in that case, amounted to willful infringement. As such, the district court found the case to be exceptional and awarded attorney fees. Specifically, the district court found that Danbury submitted a baseless ANDA certification and

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[4] Section 285 provides: "The court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285.

committed litigation misconduct. *Id.* at 1348. Notably, these conclusions were reached by the district court after the court conducted a bench trial and the patentee moved for judgment as a matter of law under Rule 52(c).

On appeal, the Federal Circuit disagreed with the district court's finding of willful infringement, but agreed that the award of attorneys fees was warranted. The Federal Circuit noted that the district court "need not have elevated the ANDA certification into a finding of willful infringement" since "[a]n ANDA filing by its very nature is a 'highly artificial act of infringement.'" *Id.* at 1347 (citing *Eli Lilly*, 496 U.S. at 678). The court acknowledged that the Patent Act "unambiguously permits an award of attorney fees to the prevailing party in exceptional cases on the basis of an ANDA filing." *Yamanouchi*, 231 F.3d at 1346 (citing 35 U.S.C. § 271(e)(4)). The court mentioned types of misconduct that would render a case "exceptional," and thus would support an award of attorney fees. These include "willful infringement, inequitable conduct before the PTO, offensive litigation tactics, vexatious or unjustified litigation, or frivolous filings." *Id.* at 1347 (citations omitted). The Federal Circuit concluded that Danbury's entire conduct, including its submission of a baseless ANDA certification and the fact that Danbury proceeded to litigate its obviousness claim despite "glaring weaknesses" in its case, supported the conclusion that the case was exceptional. *Id.*

Based on the holdings of *Glaxo* and *Yamanouchi*, it is clear that the Federal Circuit has not foreclosed the possibility of an award of attorney fees under the "exceptional case" rubric in ANDA litigation. This is permitted under 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285. The Federal Circuit has foreclosed, however, a finding of willful infringement based solely on the filing of an ANDA. While the filing of an ANDA constitutes an act of infringement, this action has been characterized

as a highly "artificial act of infringement for purposes of establishing jurisdiction in the federal courts." *Glaxo*, 376 F.3d at 1351. Thus, it would be error for a district court to hang a finding of willful infringement "on such a special-purpose peg." *Id.*

Applying these legal principles to the instant case, the Court concludes that Ranbaxy's motion to dismiss Wyeth's willful infringement claim must be granted. As contained in the four corners of the Complaint, the only alleged act of infringement Wyeth identifies is the filing of ANDA 77-484. Wyeth claims that "Ranbaxy's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, sale or importing of its Ibuprofen and Pseudoephedrine Hydrochloride Capsules, before [] the expiration of the '643 and '615 [P]atents constitutes infringement" under 35 U.S.C. § 271(e)(2). (Compl. ¶ 13). Clearly, this act by itself cannot support a willful infringement finding. Other than a conclusory assertion that "Ranbaxy's infringement has been, and continues to be, willful and deliberate," Wyeth has not alleged any other infringing conduct in the Complaint upon which a willfulness finding can be sustained. (Compl. ¶ 16).

Wyeth's argument that Ranbaxy may be held liable for willful infringement in light of certain evidence suggesting that Ranbaxy deliberately copied the claimed elements of the patents is unavailing. (Pl.'s Opp'n at 2). Wyeth fails to provide legal authority to support its proposition that the filing of an ANDA, in combination with deliberate copying of a patented invention, can amount to willful infringement. The case law cited by Wyeth in support of its argument are cases that do not concern Hatch-Waxman litigation. (*See* Pl.'s Opp'n at 8). As the Federal Circuit explained in *Yamanouchi*, a trial court need not elevate the filing of an ANDA certification to a finding of willful infringement.

More appropriately, *Yamanouchi* provides that these circumstances, e.g., the filing of an ANDA in combination with various types of misconduct, can serve as a basis for enhanced damages in the form of attorneys fees as permitted under 35 U.S.C. §§ 271(e)(4) and 285. Wyeth has properly pled its claim for attorneys fees in its Complaint. (Compl. ¶ (e)). As such, the Court concludes that while judgment on the pleadings is proper as to any willful infringement claim, Wyeth is entitled to maintain its claim for enhanced damages under 35 U.S.C. § 285, should it ultimately prevail and prove additional circumstances, other than willful infringement, that would render this case "exceptional."[5]

The Court also notes that this conclusion is consistent with the decisions reached in similar cases in this district which are cited in the parties' briefs. For example, the court in *Novartis Pharmaceuticals Corp. v. Teva Pharmaceuticals USA, Inc.*, Civ. No. 05–2887, 2005 WL 3664014 (D.N.J. Dec. 30, 2005) concluded that the innovator company was entitled to proceed with its claim that the case was "exceptional" under 35 U.S.C. § 285 for purposes of an attorneys fees award. Additionally, in *Celgene Corp. v. Teva Pharmaceuticals, USA, Inc.*, 412 F. Supp. 2d 439 (D.N.J. 2006), the court dismissed the innovator company's claim for willful infringement since the allegedly infringing conduct was limited to its ANDA filing. The court noted, however, that the

[5] The Court notes that the Federal Circuit has not held that an ANDA filer can never be liable for willful infringement as Ranbaxy seems to suggest. (*See* Defs.' Br. at 7 (arguing that "there can be no willful infringement as a matter of law in an ANDA case")). Such a reading of the *Glaxo* holding is overbroad. The Federal Circuit held that the filing of an ANDA – by itself – cannot constitute willful infringement. Presumably, there are situations where a generic company could be liable for willful infringement because it filed an ANDA *and* engaged in some other conduct that could support a willful infringement finding. Here, however, Wyeth has not alleged any such additional conduct in its Complaint. Wyeth's allegation of infringing conduct is limited to filing of ANDA 77-484. Therefore, its willful infringement claim must be dismissed in accordance with *Glaxo*.

innovator company was not prohibited from seeking attorneys fees under the "exceptional case" provision of 35 U.S.C. § 285. *Id.* at 445.

III. CONCLUSION

In light of the foregoing analysis, Ranbaxy's motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedures 12(c) is granted-in-part and denied-in-part. The Court grants judgment on the pleadings with respect to Wyeth's willful infringement claim. However, to the extent Ranbaxy moves to dismiss Wyeth's claim for attorneys fees pursuant to 35 U.S.C. § 285, that motion is denied. An appropriate form of Order accompanies this Memorandum Opinion.

Dated: August 11, 2006

s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.